



# UNITED STATES PATENT AND TRADEMARK OFFICE

cl

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,192	06/06/2002	Brigitte Desiree Alberte Colau	B45194	8137

20462 7590 10/20/2005

SMITHKLINE BEECHAM CORPORATION  
CORPORATE INTELLECTUAL PROPERTY-US, UW2220  
P. O. BOX 1539  
KING OF PRUSSIA, PA 19406-0939

EXAMINER

WANG, LOUISE Z

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/049,192	<b>Applicant(s)</b> COLAU ET AL.	
	<b>Examiner</b> Louise Wang	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 40-71 and 73-91 is/are pending in the application.
- 4a) Of the above claim(s) 40-56, 77 and 78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 57-71, 73-76 and 79-91 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

Acknowledgement is hereby made of receipt and entry of the amendment filed 22 August 2005. Claim 72 has been canceled. Claims 79-91 have been added. Claims 57-71, 73-76, and 79-91 are pending.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been entered.

### ***Election/Restrictions***

Applicant's election with traverse of Group III, claims 57-76, in the reply filed on 29 August 2005 is acknowledged. The traversal is on the grounds that Applicant disagrees with Examiner in that the common technical feature is a contribution over the prior art of Clark et al. (US 5,626,851). This is not found persuasive because the current invention lacks an inventive step over Clark *et al.* even though the current invention is restricted to human rotaviruses and is different from the human/bovine reassortants disclosed by the Clark *et al.* This modification would have been obvious to a person of ordinary skill in the art given the great interest in effective rotavirus vaccines and previous results.

Art Unit: 1648

Therefore, the restriction among the different products that may be used in the different methods is maintained. Claims 40-56, 77, and 78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

In light of the newly added claims and upon further consideration, Group III contains multiple species. In replacement of the previous restriction requirement is the following restriction:

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 40-52, drawn to an attenuated human rotavirus population comprising at least one of the rotavirus proteins.

Group II, claims 53-56, drawn to a method of production of an attenuated human rotavirus population.

Group III, claims 57-71, 73-76 and 79-91, drawn to a vaccine composition comprising a live attenuated human rotavirus and an antacid and a viscous agent.

Group IV, claim 77, drawn to drawn to a method of manufacture of a rotavirus vaccine comprising admixing a lyophilized live attenuated human rotavirus with an antacid and a viscous agent.

Group V, claim 78, drawn to a method of preventing rotavirus infection in humans by administering to a human subject in need thereof an effective amount of a vaccine.

### ***Species Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

For each Group, applicant is required to elect a viral protein from the following:

- (a) VP4;
- (b) VP7; or
- (c) VP4 and VP7.

Applicant is further required to elect a species wherein VP4 comprises at least:

- (i) an adenine base (A) at position 788;
- (ii) an adenine base (A) at position 802;
- (iii) a thymine base (T) at position 501 ; or
- (iv) an adenine base (A) at positions 788 and 802 and a thymine base (T) at position 501 from the start codon.

Applicant is also required to elect a species wherein VP7 comprises at least:

- (v) a thymine (T) at position 605;
- (vi) an adenine (A) at position 897.,
- (vii) a guanine (G) at position 897.,
- (viii) a thymine (T') at position 605 and an adenine (A) at position 897\*, or
- (iv) a thymine (T) at position 605 and a guanine (G) at position 897 from the start codon.

Art Unit: 1648

If Group III, IV, or V is elected, applicant is additionally required to elect an antacid from the following species:


- (1 ) sodium citrate;
- (2) aluminum hydroxide',
- (3) calcium carbonate.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Wang, Ph.D.  
Patent Examiner  
18 October 2005

  
**JEFFREY STUCKER**  
**PRIMARY EXAMINER**